# IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TENNESSEE MEMPHIS DIVISION

MYRA BENNETT and JAMES LEE JONGEWAARD,

PLAINTIFFS,	Case No.:
v.	JURY TRIAL DEMANDED
ZHEJIANG HUAHAI PHARMACEUTICAL	

CO., LTD, PRINSTON PHARMACEUTICIAL, INC., and SOLCO HEALTHCARE U.S., LLC,

**DEFENDANTS.** 

# **COMPLAINT**

Plaintiffs, Myra Bennett and James Lee Jongewaard, file this their complaint against Defendants Zhejiang Huahai Pharmaceutical Co., Ltd., Solco Healthcare U.S., LLC and Prinston Pharmaceutical, Inc.

## **Nature of the Action**

1. Plaintiffs file this action for personal injury damages arising out of Plaintiff Myra Bennett's use of prescription irbesartan-containing prescription medications contaminated with N-nitrosodiethylamine ("NDEA"), a carcinogenic impurity sold and manufactured by Defendants.

#### **Parties**

- 2. Plaintiff Myra Bennett is an adult resident of Tennessee, residing in Memphis, Tennessee.
- 3. Plaintiff James Lee Jongewaard is an adult resident of Tennessee, residing in Memphis, Tennessee.
- 4. Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") is a Chinese corporation, with its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

- 5. ZHP is the parent company of subsidiaries Prinston Pharmaceutical Inc. and Solco Healthcare U.S., LLC.
- 6. Defendant Prinston Pharmaceutical, Inc. ("Prinston") is a corporation organized under the laws of the State of Delaware and maintains its principal place of business at 2002 Eastpark Boulevard, Cranbury, New Jersey 08512. Defendant Prinston conducts business throughout the United States, including in the State of Tennessee. Defendant Prinston, acting in concert with Defendant Solco, manufactured and distributed contaminated irbesartan-containing medication to consumers nationwide, including contaminated irbesartan prescribed to Plaintiff Myra Bennett.
- 7. Defendant Solco Healthcare U.S., LLC ("Solco") is a limited liability company organized under the laws of the State of Delaware and maintains its principal place of business at 2002 Eastpark Boulevard, Suite A, Cranbury, New Jersey 08512. Defendant Solco is a wholly owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical Co., Ltd. Solco, acting in concert with Prinston, manufactured and distributed contaminated irbesartancontaining medication to consumers nationwide, including contaminated irbesartan medication prescribed to Plaintiff Myra Bennett.

### Jurisdiction and Venue

- 8. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a) as this is a civil action where the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs and is between citizens of different States.
- 9. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 as acts and transactions giving rise to this action occurred in this District, and because Defendants (a) are authorized to conduct business in this District and have availed themselves of the laws and the markets within

this District through the marketing, distribution and sale of contaminated irbesartan-containing medications in this District; (b) conduct substantial business within this District; and (c) are subject to personal jurisdiction in this District.

#### **Facts**

- 10. Irbesartan is a prescription medication primarily used to control high blood pressure and treat heart failure. A combination of irbesartan and hydrochlorothiazide, originally marketed under the brand name Avalide, is primarily used to control high blood pressure. Defendants manufacture, distribute and sell a generic form of irbesartan. Defendants manufacture irbesartan in laboratories located in China. During the manufacturing of irbesartan, the medication was contaminated with NDEA.
- 11. NDEA is an organic chemical. The U.S. Food and Drug Administration ("FDA") has found that NDEA is found in "air pollution, and industrial processes, and has been classified as a probable human carcinogen as per international Agency for Research on Cancer (IARC) classification." NDEA is also classified as a Group 2A carcinogen (probable human carcinogen) by the World Health Organization. NDEA is acutely toxic when consumed orally.
- 12. On May 21, 2019, the U.S. Food and Drug Administration ("FDA") announced the voluntary recall of "one (1) lot of Irbesartan and seven (7) lots of Irbesartan HCTZ Tablets to the consumer level due to the detection of trace amount of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals."<sup>2</sup> The

<sup>&</sup>lt;sup>1</sup> Company Announcement, Torrent Pharmaceuticals, Ltd., Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium and Hydrochlorothiazide Tablets, USP (Jan. 22, 2019), available at <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium</a>

<sup>&</sup>lt;sup>2</sup> Company Announcement, Prinston Pharmaceutical Inc., dba Solco Healthcare LLC, Prinston Pharmaceutical Inc. issues Voluntary Nationwide Recall of Irbesartan and Irbesartan HCTZ

medications were found to "contain N-nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA." The FDA's announcement notes that NDEA "has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification." Defendants have now recalled many lots of irbesartan, including the following medications prescribed to Plaintiff Myra Bennett: Irbesartan/HCTZ 150MG/12.5MG 90CT Tablets, NDC Code 43547-330-09, Lot Number 325B18004, and Irbesartan/HCTZ 150MG/12.5MG 30CT Tablets, NDC Code 43547-330-03, Lot Number 325D18005.5

- 13. Patients affected by the recall, including Plaintiff Myra Bennett, were instructed to "contact their pharmacists or physician who can advise them about an alternative treatment." <sup>6</sup>
- 14. Generic drugs reach the market when brand-name versions of the drug come off patent and competitors are able to seek approval for marketing and selling bioequivalent versions of the brand-name drug. Generic equivalents are required to be of equal quality and equal safety. According to the FDA, "[a]ll generic drugs approved by [the] FDA have the same high quality, strength, purity and stability as brand-name drugs."
- 15. The irbesartan-containing drugs manufactured and distributed by Defendants are likewise supposed to be equivalent to the brand-name drugs. However, Defendants' irbesartan was defectively manufactured as it was contaminated with NDEA. As such Defendants' irbesartan-

Tablets Due to detection of a Trace Amount of Unexpected Impurity, N-nitrosodiethylamine (NDEA) in the Products (Jan. 18, 2019), *available at* <a href="https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-irbesartan-hctz">https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-irbesartan-hctz</a>.

 $<sup>^3</sup>$  Id.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> *Id*.

<sup>&</sup>lt;sup>6</sup> *Id*.

<sup>&</sup>lt;sup>7</sup> https://www.fda.gov/drugs/generic-drugs/overview-basics (last accessed June 5, 2019).

containing medications were neither safe nor of equal quality to the brand-name version of the medication.

16. Defendant Solco, which is in the business of marketing and distributing generic pharmaceuticals, states on its website:

Generic pharmaceuticals are identical (bioequivalent) to the branded medications with regard to:

- Intended Use
- Effectiveness
- Dosage form
- Strength
- Safety
- Routine administration
- Quality<sup>8</sup>

#### 17. Defendant Solco's website further states:

Our products are manufactured in state-of-the-art GMP facilities in China using the highest quality assurance standards that meet the FDA regulatory requirements. Solco is a fully owned subsidiary of Prinston Pharmaceutical, Inc. and Zhejiang Huahai Pharmaceutical, leaders in drug development and manufacturing of active pharmaceutical ingredients (API) and finished dosages products. Together we strive to offer greater access to affordable medications that you can trust.<sup>9</sup>

- 18. Further, the labeling, packaging and associated documentation provided with the medication prescribed to, taken by and relied upon by Plaintiff Myra Bennett, represented that the medication contained only those ingredients and properties stated on the label, which did not include the carcinogenic impurity NDEA.
- 19. Each of the representations and warranties made by Defendant Solco were false.

  Defendants knew that the irbesartan-containing medications were not of equal quality and safety as compared to brand-name irbesartan, and that the API was manufactured in a facility with a

<sup>&</sup>lt;sup>8</sup> http://www.solcohealthcare.com/about-solco.html (last accessed June 5, 2019).

<sup>&</sup>lt;sup>9</sup> *Id*.

history of quality control issues. In fact, Defendant ZHP, the overseas supplier and parent company of Defendants Solco and Prinston, has recently been placed on import alert by the FDA, which stops all API and finished drug products using API produced by the company from entering the United States.<sup>10</sup>

- 20. Prior to Defendants Solco and Prinston's recalls of their irbesartan-containing medications, they were implicated in a recall of a related ARB medication, valsartan. Valsartan is also used to treat high blood pressure and heart failure and is manufactured by Defendant ZHP.
- 21. The July 13, 2018 recall of the related valsartan medication was due to the presence of a related carcinogen, N-nitrosodimethylamine ("NDMA"). The NDMA contamination in the related valsartan medications was due to a manufacturing defect, caused by changes in the way the active substance was manufactured.
- 22. Despite knowledge of the manufacturing defect in the closely-related valsartan medication, Defendants continued to manufacture and sell irbesartan medication in the United States, and waited to announce a recall until over six months later.
- 23. On November 29, 2018, the FDA issued a warning letter to Defendant ZHP following an inspection of its manufacturing facility from July 23 to August 3, 2018.<sup>11</sup> The letter summarized "significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API)."<sup>12</sup>

<sup>&</sup>lt;sup>10</sup> FDA, Import Alert 66-40, May 29, 2019, *available at* https://www.accessdata.fda.gov/cms\_ia/importalert\_189.html

<sup>&</sup>lt;sup>11</sup> FDA, Warning Letter to Zhejiang Huahai Pharmaceutical, Nov. 11, 2018, *available at* <a href="https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018">https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/zhejiang-huahai-pharmaceutical-566685-11292018</a>

<sup>12</sup> *Id.* 

- 24. The FDA noted that Defendant ZHP's "API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351 (a)(2)(B)."<sup>13</sup>
- 25. The FDA mentioned two major findings in its letter. First, the FDA noted the "[f]ailure of [ZHP's] quality unit to ensure that quality-related complaints are investigated and resolved."<sup>14</sup> The letter then proceeded to explain how Defendant ZHP had knowledge of the NDMA contamination from customer complaints in 2016 and 2018, but ignored them for the sake of increasing profits:

#### Valsartan API

Your firm received a complaint from a customer on June 6, 2018, after an unknown peak was detected during residual solvents testing for valsartan API manufactured at your facility. The unknown peak was identified as the probable human carcinogen N-nitrosodimethylamine (NDMA). Your investigation (DCE-18001) determined that the presence of NDMA was caused by the convergence of three process-related factors, one factor being the use of the solvent (b)(4)). Your investigation concluded that only one valsartan manufacturing process (referred to as the (b)(4) process in your investigation) was impacted by the presence of NDMA.

However, FDA analyses of samples of your API, and finished drug product manufactured with your API, identified NDMA in multiple batches manufactured with a different process, namely the (b)(4) process, which did not use the solvent (b)(4). These data demonstrate that your investigation was inadequate and failed to resolve the control and presence of NDMA in valsartan API distributed to customers. Your investigation also failed:

- To include other factors that may have contributed to the presence of NDMA. For example, your investigation lacked a comprehensive evaluation of all raw materials used during manufacturing, including (b)(4).
- To assess factors that could put your API at risk for NDMA cross-contamination, including batch blending, solvent recovery and re-use, shared production lines, and cleaning procedures.

<sup>&</sup>lt;sup>13</sup> *Id*.

<sup>&</sup>lt;sup>14</sup> *Id*.

• To evaluate the potential for other mutagenic impurities to form in your products.

Our investigators also noted other examples of your firm's inadequate investigation of unknown peaks observed in chromatograms. For example, valsartan intermediates  $(\mathbf{b})(4)$  and  $(\mathbf{b})(4)$  failed testing for an unknown impurity (specification  $\leq (\mathbf{b})(4)\%$ ) with results of  $(\mathbf{b})(4)\%$  for both batches. Your action plan indicated that the impurity would be identified as part of the investigation; however, you failed to do this. In addition, no root cause was determined for the presence of the unknown impurity. You stated that you reprocessed the batches and released them for further production.

Your response states that NDMA was difficult to detect. However, if you had investigated further, you may have found indicators in your residual solvent chromatograms alerting you to the presence of NDMA. For example, you told our investigators you were aware of a peak that eluted after the (b)(4) peak in valsartan API residual solvent chromatograms where the presence of NDMA was suspected to elute. At the time of testing, you considered this unidentified peak to be noise and investigated no further. Additionally, residual solvent chromatograms for valsartan API validation batches manufactured using your (b)(4) process, with (b)(4) in 2012 ((b)(4), and (b)(4)) show at least one unidentified peak eluting after the (b)(4) peak in the area where the presence of NDMA was suspected to elute.

Your response also states that you were not the only firm to identify NDMA in valsartan API. In your case, FDA analyses of samples identified amounts of NDMA in valsartan API manufactured at your firm that were <u>significantly higher than the NDMA levels in valsartan API manufactured by other firms.</u> FDA has grave concerns about the potential presence of mutagenic impurities in all intermediates and API manufactured at your facility, both because of the data indicating the presence of impurities in API manufactured by multiple processes, and because of the significant inadequacies in your investigation.<sup>15</sup>

#### The letter continues:

(b)(4) API

Your firm received a customer complaint on September 13, 2016, concerning (b)(4) API batches ((b)(4) and (b)(4)) that exceeded the specification for (b)(4) (≤ (b)(4)ppm). (b)(4) has been classified as a probable human carcinogen. Your customer's test results conflicted with your (b)(4) test results, which showed the two batches meeting the specification upon release. Your complaint investigation (CC-16008) identified no clear laboratory error, and no anomalies were detected during the production of the batches. Your investigation failed to evaluate other (b)(4) API batches to determine if the presence of excess (b)(4) was an adverse trend. For example, (b)(4) batches (b)(4), and (b)(4) were OOS for (b)(4) because

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<sup>&</sup>lt;sup>15</sup> *Id*.

of production errors; however, they were not discussed in your complaint investigation.

Your response states that (b)(4) API batches (b)(4) and (b)(4) were returned, reprocessed, and released to customers in non-U.S. markets.

Your response also states that in August 2017 you implemented a new (b)(4) test method that uses a (b)(4) LC-MS/MS method, to replace the (b)(4) LC-MS method that was prone to erroneous OOS results. You failed to verify the reliability of the (b)(4) results for all (b)(4) API batches (including (b)(4) batch (b)(4)) originally released using your (b)(4) LC-MS method, which you indicated was inferior to your updated method.<sup>16</sup>

26. The second major finding noted by the FDA was Defendant ZHP's "[f]ailure to evaluate the potential effect that changes in the manufacturing process may have on the quality of [its] API."<sup>17</sup> This aspect of the letter revealed that the API contamination likely dates back to November of 2011, and that Defendant ZHP switched to the new process to increase profit despite the fact that the new, unproven process rendered much greater risk of impurities such as NDMA.

In November 2011 you approved a valsartan API process change (PCRC - 11025) that included the use of the solvent (b)(4). Your intention was to improve the manufacturing process, increase product yield, and lower production costs. However, you failed to adequately assess the potential formation of mutagenic impurities when you implemented the new process. Specifically, you did not consider the potential for mutagenic or other toxic impurities to form from (b)(4) degradants, including the primary (b)(4) degradant, (b)(4). According to your ongoing investigation, (b)(4) is required for the probable human carcinogen NDMA to form during the valsartan API manufacturing process. NDMA was identified in valsartan API manufactured at your facility.

You also failed to evaluate the need for additional analytical methods to ensure that unanticipated impurities were appropriately detected and controlled in your valsartan API before you approved the process change. You are responsible for developing and using suitable methods to detect impurities when developing, and making changes to, your manufacturing processes. If new or higher levels of impurities are detected, you should fully evaluate the impurities and take action to ensure the drug is safe for patients.

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>&</sup>lt;sup>17</sup> *Id*.

Your response states that predicting NDMA formation during the valsartan manufacturing process required an extra dimension over current industry practice, and that that your process development study was adequate. We disagree. We remind you that common industry practice may not always be consistent with CGMP requirements and that you are responsible for the quality of drugs you produce.

Your response does not describe sufficient corrective actions to ensure that your firm has adequate change management procedures in place: (1) to thoroughly evaluate your API manufacturing processes, including changes to those processes; and (2) to detect any unsafe impurities, including potentially mutagenic impurities.<sup>18</sup>

- 27. Based on the egregious deficiencies listed above, the FDA recommended that Defendant ZHP engage a consultant "to evaluate your operations and assist your firm in meeting CGMP requirements." <sup>19</sup>
- 28. The FDA also placed Defendant ZHP on import alert following its inspection, which stops all API and finished products using API produced by the company from entering the United States.
- 29. Indeed, FDA Commissioner Scott Gottlieb commented: "The issues cited in the warning letter are associated with the nitrosamine impurities found in these drugs, and these violations reveal a disturbing lack of oversight at this API manufacturer that puts patients at risk."<sup>20</sup>
- 30. Despite these warnings related to their closely-related valsartan medication, Defendants Solco and Prinston failed to take any quality control measures related to their irbesartan medication.

<sup>&</sup>lt;sup>18</sup> *Id*.

<sup>&</sup>lt;sup>19</sup> *Id*.

<sup>&</sup>lt;sup>20</sup> Ben Hargreaves, *US FDA notes 'disturbing lack of oversight' over valsartan contamination*, in-Pharmatechnologist.com (Dec. 12, 2018), <a href="https://www.in-pharmatechnologist.com/Article/2018/12/12/US-FDA-notes-disturbing-lack-of-oversight-over-valsartan-contamination">https://www.in-pharmatechnologist.com/Article/2018/12/12/US-FDA-notes-disturbing-lack-of-oversight-over-valsartan-contamination</a>.

- 31. Defendants Solco and Prinston's conduct is especially egregious as they and their parent company, Defendant ZHP, were on notice of the contamination as early as 2016.
- 32. In failing to act, Defendants knowingly and with an intent to defraud, concealed from Plaintiffs the material facts concerning Defendant ZHP's pervasive CGMP violations, and made express and implied representations to Plaintiff Myra Bennett that their irbesartan medications conformed to applicably standards of quality, purity, identity and strength, were not adulterated, and were merchantable, fit for human consumption, and fit for their intended purpose when, in fact, the irbesartan medications were contaminated with NDEA, a probable human carcinogen.
- 33. Defendants' irbesartan medications sold in the United States contained a printed insert which represented that the drug in the package had the specified properties, conformed to the specified description, and carried a guarantee of quality assurance. Defendants Solco and Prinston knowingly made these representations with actual knowledge, or reason to know, that they were false, because Defendants Solco and Prinston had outsourced production to a Chinese company that was committing egregious CGMP violations, resulting in contaminated API.
- 34. Plaintiff Myra Bennett first began taking Defendants' irbesartan products in April of 2015, and was prescribed Irbesartan/HCTZ 150-12.5 tablets for her high blood pressure.
  - 35. Plaintiff Myra Bennett took irbesartan as prescribed.
- 36. In January of 2016, Plaintiff Myra Bennett was diagnosed with bladder cancer. Plaintiff Myra Bennett had surgery to remove the malignant bladder tumor and underwent chemotherapy, but ultimately had to have her entire bladder removed.

#### **COUNT I**

## MANUFACTURING DEFECT PURSUANT TO T.C.A. §§ 29-28-101 et. seq.

- 37. Plaintiffs hereby incorporate by reference the allegations in all preceding paragraphs of this Complaint as if fully set forth herein.
- 38. At all times relevant, the contaminated irbesartan purchased and ingested by Plaintiff Myra Bennett was defective as it was in a condition that rendered it unsafe for consumption as prescribed.
- 39. The NDEA contamination by Defendants during their manufacturing process led to irbesartan medications containing the harmful impurity NDEA. NDEA was not intended to be included in the medication; it was an impurity that was created due to an error in the manufacturing process.
- 40. As a proximate cause of Defendants' defective manufacturing process and contamination of irbesartan-containing products, which Plaintiff Myra Bennett took as prescribed, Plaintiff Myra Bennett suffered serious personal injury and damages, including bladder cancer, requiring surgery and further resulting in permanent, ongoing injury, damages and pain and suffering.
- 41. Because the irbesartan medications manufactured, distributed and sold by Defendants suffered from a manufacturing defect which caused Plaintiff Myra Bennett immediate and proximate harm, Defendants are strictly liable to Plaintiff Myra Bennett for her damages.
- 42. As a result of the foregoing, Defendants caused Plaintiff Myra Bennett to suffer severe injuries including bladder cancer, as well as economic and non-economic damages, including, but not limited to: medical expenses, psychological injury, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

# **COUNT II**

## DESIGN DEFECT PURSUANT TO T.C.A. §§ 29-28-101 et. seq.

- 43. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.
- 44. At all times relevant herein, Defendants designed, researched, manufactured, tested advertised, promoted, marketed, sold, and distributed adulterated irbesartan as hereinabove described, which was used by Plaintiff Myra Bennett.
- 45. Adulterated irbesartan was expected to and did reach consumers without substantial change in the condition in which it was produced, manufactured, distributed, marketed and sold by Defendants.
- 46. At the time that Plaintiff Myra Bennett used the adulterated irbesartan, the adulterated irbesartan was being used by Plaintiff Myra Bennett for the purposes and in the manner prescribed.
- 47. At those times, the adulterated irbesartan was in an unsafe, defective and inherently dangerous condition, which was dangerous to users, including Plaintiff Myra Bennett, because it was contaminated by NDEA, a carcinogen.
- 48. At all times relevant, Defendants knew or had reason to know that the adulterated irbesartan was defective and unsafe.
- 49. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.
- 50. In creating the adulterated irbesartan, Defendants created a product that was inherently dangerous for its normal, intended use, and safer alternative design existed, namely a properly designed and manufactured irbesartan medication.

- 51. The adulterated irbesartan designed, researched, manufactured, tested, advertised, promoted, distributed, marketed and sold by Defendants reached intended users, including Plaintiff Myra Bennett, in the same defective and unreasonably dangerous condition in which the adulterated irbesartan was designed and manufactured.
- 52. Defendants' irbesartan products, as designed, were defective so as to create an unreasonable risk to the health of consumers, including Plaintiff Myra Bennett, and Defendants are liable for damages for the injuries to Plaintiff Myra Bennett.
- 53. The adulterated irbesartan designed, researched, manufactured, tested, advertised, promoted, marketed, and distributed by Defendants was defective in design or formulation, in that when it left the hands of Defendants, the foreseeable risks exceeded the benefits associated with the product.
- 54. Plaintiff Myra Bennett could not, by the exercise of reasonable care, have discovered the adulterated irbesartan defects and perceived its danger.
- 55. Defendants' defective design of the adulterated irbesartan was willful, wanton and/or reckless.
- 56. As a result of the foregoing acts and omissions, Defendants caused Plaintiff Myra Bennett to suffer severe person injury, including bladder cancer, as well as economic and non-economic damages, harms and losses, including, but not limited to medical expenses, psychological injuries, mental anguish and anxiety, severe emotional distress, pain and suffering and loss of enjoyment of life.

## **COUNT III**

### **NEGLIGENCE**

- 57. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.
- 58. The Defendants supplied, manufactured, promoted, marketed, distributed and/or sold irbesartan as a drug for consumption by consumers, including Plaintiff Myra Bennett.
- 59. Defendants had a duty to exercise ordinary care to supply, manufacture, distribute and/or sell irbesartan to Plaintiff Myra Bennett which was not adulterated.
  - 60. Defendants breached their duty of care owed to Plaintiff Myra Bennett by:
    - a. Supplying, manufacturing, promoting, marketing, distributing and/or selling irbesartan that was adulterated because it was contaminated by NDEA, a carcinogen; and
    - b. Failing to maintain appropriate quality control procedures thereby allowing NDEA to contaminate irbesartan prescribed to and taken by Plaintiff Myra Bennett.
- 61. Defendants' breach of the duty of care proximately caused damage to Plaintiff Myra Bennett by causing her to suffer serious injuries, including cancer.
- 62. Each Defendant had an obligation to exercise reasonable care in manufacturing, marketing, promoting, selling, and distributing highly dangerous adulterated irbesartan to Plaintiff Myra Bennett.
- 63. Each Defendant owed a duty to Plaintiff Myra Bennett because her use and potential for injury was foreseeable.
- 64. Defendants breached their duties to exercise due care in their business of the manufacture, distribution and sale of irbesartan by failing to monitor and report contamination in their medications.

65. Defendants' breaches of their duties were the cause in fact of Plaintiff Myra Bennett's injuries.

### **COUNT IV**

# LOSS OF CONSORTIUM PURSUANT TO T.C.A. § 25-1-106

- 66. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this Complaint as if fully set forth herein.
- 67. Plaintiffs Myra Bennett and James Lee Jongewaard were lawfully married at all times relevant to this action, and are husband and wife.
- 68. As alleged above, and as a result of the conduct of the Defendants, Plaintiff Myra Bennett sustained severe and permanent injuries and damages.
- 69. As a direct and proximate result of the afore-mentioned injuries suffered by Plaintiff Myra Bennett, Plaintiff James Lee Jongewaard has been deprived, continues to be deprived, and expects to be deprived in the future, of his spouse's companionship, affection, love, sexual relations, conjugal fellowship, physical assistance in maintaining the family home and comfort for a non-determinable length of time, which deprivation has caused, continues to cause, and in the future is expected to cause Plaintiffs to suffer depression, emotional distress, loss of earning capacity, past, present, and future, and other injuries, the full extent of which has not yet been ascertained, but which will be stated according to proof at trial.
- 70. As a further direct and proximate result of the aforesaid conduct of Defendants, and each of them, Plaintiff James Lee Jongewaard has sustained a loss of consortium, love, society, comfort, and affection with respect to Plaintiff Myra Bennett and has thereby sustained pecuniary loss in a some within the jurisdictional limits of the Court, which will be stated according to proof at trial.

## **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

- a. For general non-economic damages;
- b. For medical expenses and other economic damages;
- c. For prejudgment interest;
- d. For damages for Plaintiffs' other economic and non-economic losses;
- e. For damages for loss of consortium, as to James Lee Jongewaard;
- f. For costs of litigation and trial;
- g. For attorney fees; and
- h. For such other and further relief as the Court may deem just and proper.

## JURY TRIAL DEMANDED

Plaintiffs request a trial by jury.

Dated: July 1, 2019 Respectfully submitted,

/s/ David M. McMullan, Jr.

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